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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,521	03/19/2001	Caroline Kreutzer	P 278416 980183 BT-CIP	6186

909 7590 03/12/2002

PILLSBURY WINTHROP LLP  
1600 TYSONS BOULEVARD  
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EXAMINER
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STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 03/12/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/810,521

Applicant(s)

KREUTZER ET AL.

Examiner

David J. Steadman

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

**DETAILED ACTION**

***Application Status***

Claims 1-26 are pending in the application.

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claim(s) 1-4, 16, 19, 20, 22, and 23, drawn to a corynebacteria with an enhanced *pyc* gene in addition to enhanced *dapA*, *lysC*, and/or *lysE* genes, wherein the *dapA* gene has the promoter of SEQ ID NO:5 (MC20) or SEQ ID NO:6 (MA16), the *Escherichia coli* of Deposit Number DSM12872, the corynebacteria of Deposit Numbers DSM 12868 and DSM 12867, and the polynucleotides of SEQ ID NOs:5 and 6, classified in class 435, subclass 252.32.
  - II. Claim(s) 1-3, 5-8, 16-18, and 21, drawn to a corynebacteria with an enhanced *pyc* gene in addition to enhanced *dapB*, *lysC*, and/or *lysE* genes, wherein the *dapB* gene has the 5' upstream non-coding sequence of SEQ ID NO:1, the *Escherichia coli* of Deposit Numbers DSM12872, DSM12875, DSM12873, DSM12874, classified in class 435, subclass 252.32.
  - III. Claim(s) 9-15 and 24-26, drawn to a process for the preparation of L-lysine using a corynebacteria with an enhanced *pyc* gene in addition to enhanced *dapA*, *lysC*, and/or *lysE* genes, classified in class 435, subclass 115.
  - IV. Claim(s) 9, 11-15, 24, and 26, drawn to a process for the preparation of L-lysine using a corynebacteria with an enhanced *pyc* gene in addition to enhanced *dapB*, *lysC*, and/or *lysE* genes, classified in class 435, subclass 115.
2. The inventions are distinct, each from the other because:
3. The corynebacteria of Groups I and II each expresses chemically unrelated enzymes capable of separate manufacture, use and effect. The corynebacteria of Group I can be used for expression of the *dapA* gene and the corynebacteria of Group II can be used for expression of the *dapB* gene.

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4. The corynebacteria of Groups I and II and the processes of Groups III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the corynebacteria of Groups I and II can be used for plasmid propagation or gene expression and process of producing L-lysine can be performed with corynebacteria other than the corynebacteria of Groups I and II.

5. The methods of Groups III and IV are independent as they utilize different products.

6. Because these inventions are distinct for the reasons given above and each of the inventions listed as Groups I-IV requires a separate search, restriction for examination purposes as indicated is proper. "For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP 808.02" (see MPEP 803). The inventions listed as Groups I-IV require divergent patent and non-patent literature and/or sequence searches, and co-examination of the inventions of Groups I-IV would result in a serious burden on the examiner.

7. Claims 1-3, 9, 11, 13, 24, and 26 will be examined to the extent the claims read on the elected subject matter.

8. It is noted that claim 8 recites "[t]he DNA as claimed in claim 5", however, claim 5 is drawn to a corynebacteria and not a DNA. It appears that claim 8 should be dependent upon either of claims 6 or 7 and has been grouped for restriction purposes accordingly and it is suggested that applicants amend the claim for proper dependency.

### ***Conclusion***

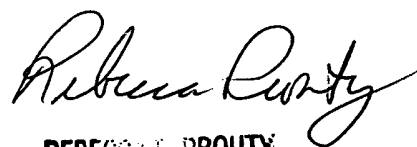
9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:30 am to 2:00 pm and from 3:30 pm to 5:30 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.

  
**REBECCA L. PROUTY**  
**PRIMARY EXAMINER**  
**GROUP 1800**  
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